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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Boris Warnack

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EXAMINER

THANH, LOAN H

ART UNIT

PAPER NUMBER

3763

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

04/18/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No. 10/523,897	Applicant(s) WARNACK ET AL.	
	Examiner LoAn H. Thanh	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12 and 14-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 22-30 is/are allowed.
- 6) ☒ Claim(s) 12 and 15-21 is/are rejected.
- 7) ☒ Claim(s) 14 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 January 2007 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

The drawing filed 01/22/07 has not been approved by the Examiner. Applicant cannot add new matter to the drawings. The catheter tip should have different hatch marks. Applicant should only refer to the tip by the reference numeral 20 as amended in the specification. The drawing objection is still being maintained below until applicant submits a corrected drawing on fig. 6.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the at least one marker disposed at the catheter tip (claim 21) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering

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of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

Claims 14-21 are objected to because of the following informalities:

Renumbered claims 14-21 depend on canceled claim 1. It is the assumption that all renumbered claims depend on claim 12. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 12, 17-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Sugiyama et al. (EP 0 597 506).

Sugiyama et al. disclose a catheter having a balloon , an outer tube, inner tube and radiopaque coil markers 14. The marker is gold, platinum, tungsten or alloy of them or silver-palladium alloy. The marker is disclosed for confirming the location of the

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balloon under x-ray. See figures 1 and 13 and col.3, lines 29-39 and col. 12, lines 12-37.

Claims 12, 16,18-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Enger (US 6,129,708).

Enger discloses a balloon catheter having a radiopaque marker 35, which is covered by a thin tube like cover/sleeve 37. See figure 8 and col. 5, lines 55-65. Figure 5 specifically shows a coil-like marker. With respect to the functional language, it is the Examiner's position that the device of Enger is capable of performing the function.

Claims 12,17,20 are rejected under 35 U.S.C. 102(b) as being anticipated by Onishi et al. (US5,547,472).

Onishi et al. discloses a balloon catheter having an outer tube 3, inner tube 2 ,an inflation lumen 7, a guidewire lumen 5 and coil springs 11 or platinum marker for confirming the positioning of the balloon 4. See figure 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 12,15-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Onishi et al. (US 5,547,472) in view of Lee et al. (US 6,520,934).

Onishi et al. disclose the invention as substantially claimed. See above. Onishi et al. teaches coiled markers which are visible under x-ray. However, Onishi et al. does not teach the specifics of the wire being embedded in the inner tube, covered by a thin tube-like cover, the wire having a flat rectangular cross-section or the specific materials of the wire. Lee et al. teach a coiled wire, that is embedded in the catheter shaft, made of platinum, gold, tantalum, and alloys of there of. (See col. 3, line 21 – col. 4, line 32.) Lee et al. also teach different structures of the markers. (See figures 1-7.) Lee et al. teach markers in the analogous art of balloon catheters. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the radiopaque markers of Onishi et al. with the markers taught by Lee et al. in order to provide a more flexible radiopaque marker, a smaller diameter and hence a smaller profile for traversing and facilitate navigation of the balloon catheter under the visual guidance.

Claims 12,15-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Onishi et al. (US 5,547,472) in view of Mueller, Jr. (4,938,220) .

Onishi et al. disclose the invention as substantially claimed. However, Onishi et al. is silent to a radiopaque marker at the catheter tip. Mueller, Jr. discloses a balloon catheter with a radiopaque marker at the distal tip in the analogous art of visible markers for permitting positioning of balloon catheters. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the catheter

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of Onishi et al. to include a radiopaque marker at the catheter tip as taught by Mueller, Jr. in order to visually detect the tip of the catheter when guiding the catheter through the body.

Allowable Subject Matter

Claim 14 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 22-30 are allowable. The prior art of record fails to teach or render obvious a catheter in combination with all the elements and a radiopaque wire which is wrapped in a plurality of at least partially overlapping layers.

Response to Arguments

Applicant's arguments filed 01/22/07 have been fully considered but they are not persuasive. With respect to the Sugiyama reference, Applicant argues that the wire coil prevents the inner tube from flexing or collapsing. In col.12, lines 27-31. The Examiner agrees that Sugiyama discloses this in the specification as applicant referenced the citation. However, the prior art should be read in its full disclosure and not in a vacuum. Sugiyama discloses a balloon catheter for use in the tortuous blood vessels. It would be extremely difficult to insert Sugiyama's balloon catheter through the blood vessel if applicant's assertion was correct. In view of Sugiyama's disclosure, it is the Examiner's position that Sugiyama intends to have flexibility in the catheter

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however to avoid extreme flexion and meandering as Sugiyama discloses in col.3, lines 29-39. The flexibility in the catheter is not decreased but an extreme flexion or bend of the catheter is prevented.

With respect to the Enger reference, it is the Examiner's position that Enger is capable of performing the function as claimed.

The Omaleki et al. reference has been withdrawn in view of the amendment filed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to LoAn H. Thanh whose telephone number is (571) 272-4966. The examiner can normally be reached on Mon. - Fri. (First Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/LoAn H. Thanh/

LoAn H. Thanh
Primary Examiner
Art Unit 3763

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